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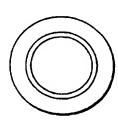
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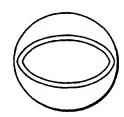
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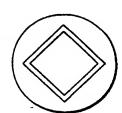
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(54) Title: ROTATIONALLY STABILIZED CONTACT LENSES





(57) Abstract: The invention provides contact lenses that incorporate a coaxial stabilization zone to stabilize the orientation of the lens in relation to the eye.











For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

ROTATIONALLY STABILIZED CONTACT LENSES

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Field of the Invention

The invention relates to contact lenses. In particular, the invention provides contact lenses that incorporate a coaxial stabilization zone to stabilize the orientation of the lens in relation to the eye.

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Background of the Invention

It is known that the correction of certain optical defects can be accomplished by imparting non-spherical corrective characteristics into a contact lens, such as cylindrical, bifocal, or multifocal characteristics. Additionally, advances in technology permit production of lenses customized to a particular wearer using topographic and wave front measurements. The use of customized contact lenses or lenses with certain corrective characteristics may be problematic in that the lens may need to be maintained at a specific orientation while on the eye to be effective. However, the lenses will rotate on the eye due to blinking as well as eyelid and tear fluid movement.

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Lenses designed to maintain their on-eye orientation typically are of two general types. One type uses prism stabilization, or thickening of certain lens portions, to maintain orientation. Examples of prism stabilization methods include decentering the front relative to the back lens surface, prismatic balancing, thickening of the lower lens edge, supporting the lens on the lower eyelid, forming depressions or elevations on the lens' surface, and truncating the lens edge.

A second lens type, dynamically stabilized lenses, uses the movement of the eyelids to maintain lens orientation. Dynamic stabilization methods include reducing the thickness of the lens' outer surface at two symmetrically lying regions, thickening two outer regions in the horizontal center axis, and thinning, or slabbing off, top and bottom zones on the lens.

The known methods for maintaining lens orientation suffer from a number of disadvantages including that lenses incorporating the methods require specialized, off-axis tooling for production, that these lenses are uncomfortable to wear, and that the known methods are not highly effective. Thus, a need exists for a method of maintaining angular orientation that overcomes some of these disadvantages.

Brief Description of the Drawings

FIG. 1 illustrates a plan view of the convex surface of a number of embodiments of the lenses of the invention.

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Detailed Description of the Invention and Preferred Embodiments
It is a discovery of the invention that rotationally stabilized contact lens may be obtained by incorporating a coaxial stabilization zone into a lens. The invention provides an effective method, and lenses incorporating that method, for on-eye lens stabilization. Additionally, the lenses may be produced using a computer numerically controlled coding without the need for specialized, off-axis tooling.

In one embodiment, the invention provides a method for producing contact lenses comprising, consisting essentially of, and consisting of: a.) defining a coaxial stabilization zone for at least one surface of a contact lens; b.) determining parameters for at least one area of thickness within the coaxial stabilization zone; and c.) calculating a surface design for the at least one surface. In another embodiment, the invention provides a contact lens comprising, consisting essentially of, and consisting of at least one coaxial stabilization zone.

The lenses of the invention may be either hard or soft contact lenses.

Preferably, the lenses are soft contact lenses. The stabilization zone may be located on the convex, or front surface, the concave, or back surface, or both surfaces.

Preferably, the zone is on the convex surface. Further, the lenses of the invention

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may have any of a variety of corrective optical characteristics incorporated onto either or both the convex and concave surfaces. For example, the lens may have any one or more of spheric, aspheric, bifocal, multifocal, prismatic, or cylindric corrections, or combinations thereof. Additionally, the surfaces may be surfaces calculated from topographic measurements, or topographically—derived surfaces, surfaces calculated from wave front measurements, and the like and combinations thereof.

The invention may find its greatest utility in customized lenses or lenses in which at least one of the corrective characteristics requires that the on-eye orientation of the lens with respect to the eye remains stable in one position. In the first step of the method of the invention, the stabilization zone is defined meaning that its shape, size, and location are defined. Any shape may be used for the coaxial stabilization zone including, without limitation, a shape that is circular, ovoid, rhomboid, triangular, and the like. Referring to FIG. 1, a number of the wide variety of possible shapes are shown.

Preferably, the stabilization zone will assume a substantially circular shape. The location of the zone on the lens typically extends from a point outside of the optic zone to a point inside of the lens edge. Preferably, the zone extends from about 0 mm outside of the optic zone to about 1 mm inside of the lens edge, more preferably from about 1 mm outside of the optic zone to about 1 mm inside of the lens edge.

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In a second step, the number of areas of thickness, and the parameters for each area, within the coaxial zone are determined. More specifically, the location and contour of the thickness areas are determined. The thickness areas may be located at any axis. However, if the lens is a toric lens, or a lens with cylinder power, preferably a single thickness area will be located at or near the about 270° axis or two thickness areas will be located at about the 0 and 180° axes. For

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customized wave-front or topography lenses, preferably one thickened area will be used, the area located at or near the about 270° axis. If more than one area of thickness are used, the thickness areas each may be about the same radial distance from the lens' center or this distance may vary.

To determine the contour of the thickened area, any periodic function may be used that provides the desired contour. Typically, the contour will be either a single or double peak. Suitable periodic functions include, without limitation, linear functions and their derivatives, sine or cosine functions and their derivatives, exponential functions, Gaussian functions, conic functions such as circles, ellipses, parabolas, hyperbolas, and the like, cycloid functions, splines, polynomial functions of any order, filter functions, notch functions, bandpass filter functions, Witch of Agnesi functions, hyperbolic trigonometric functions, catenary functions, and the like, and combinations thereof. Preferably, a linear function to exponential values, a sine or cosine phase shifted exponential function, a Gaussian function, or an Agnesi function is used. The maximum thickness of the thickened areas may be about 100 to about 300, preferably about 100 to about 175 μm.

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The lenses of the invention may be produced by any conventional method for producing contact lenses. For example, the lens design may be cut into a metal and the metal used to produce plastic mold inserts for the lens' surfaces. A suitable liquid resin is then placed between the inserts, the inserts compressed, and the resin cured to form the lens. Alternatively, the lens of the invention may be produced by cutting the lens on a lathe. One ordinarily skilled in the art will recognize that an advantage of the invention is that the lenses may be produced by the use of on-axis CNC lathing of the lenses or mold tools to produce the lenses.

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Preferably, the material selected for forming the lenses of the invention is a material suitable for forming soft contact lenses. Suitable materials for forming such contact lenses using the method of the invention include, without limitation, silicone elastomers, silicone-containing macromers including, without limitation, those disclosed in United States Patent Nos. 5,371,147, 5,314,960, and 5,057,578 incorporated in their entireties herein by reference, hydrogels, silicone-containing hydrogels, and the like and combinations thereof. More preferably, the surface is a siloxane, or contains a siloxane functionality, including, without limitation, polydimethyl siloxane macromers, methacryloxypropyl polyalkyl siloxanes, and mixtures thereof, silicone hydrogel or a hydrogel, such as etafilcon A.

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What is claimed is:

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- 1. A contact lens comprising a convex surface, a concave surface, and at least one coaxial stabilization zone.
- 2. The lens of claim 1, wherein the at least one coaxial stabilization zone is on the convex surface, the concave surface, or both surfaces.
 - 3. The lens of claim 1, wherein the coaxial stabilization zone is on the convex surface.
- 15 4. The lens of claim 1, wherein the coaxial stabilization zone is substantially circular in shape.
 - 5. The lens of claim 1, wherein the coaxial stabilization zone extends from about 0 mm outside of the optic zone to about 1 mm inside of the lens edge.

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- 6. The lens of claim 1, wherein the surface on which the coaxial stabilization zone is located is a surface calculated from topographic measurements, wavefront measurements, or combinations thereof.
- The lens of claim 1, wherein the surface on which the coaxial stabilization zone is located is a surface calculated from topographic measurements
 - 8. The lens of claim 1, wherein the surface on which the coaxial stabilization zone is located is a surface calculated from wavefront measurements.

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9. The lens of claim 6, 7, or 8, wherein the coaxial stabilization zone comprises a single thickened area at about the 270° axis.

10. The lens of claim 9, wherein the thickened area is of a thickness of about 100 to about 300 μ .

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11. A contact lens comprising a convex surface, a concave surface, and at least one coaxial stabilization zone located on one or both of the convex and concave surfaces, wherein the surface on which the coaxial stabilization zone is located is a surface calculated from topographic measurements, wavefront measurements, or combinations thereof.

12. The lens of claim 11, wherein the coaxial stabilization zone is on the convex surface.

- 15 13. The lens of claim 11, wherein the surface on which the coaxial stabilization zone is located is a surface calculated from topographic measurements
 - 14. The lens of claim 11, wherein the surface on which the coaxial stabilization zone is located is a surface calculated from wavefront measurements.

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- 15. The lens of claim 11, 13, or 14, wherein the coaxial stabilization zone comprises a single thickened area at about the 270° axis.
- 16. The lens of claim 11, wherein the coaxial stabilization zone is substantially circular in shape.
 - 17. The lens of claim 11, wherein the coaxial stabilization zone extends from about 0 mm outside of the optic zone to about 1 mm inside of the lens edge.
- 30 18. A contact lens comprising a convex surface, a concave surface, and at least one coaxial stabilization zone located on the convex surface and extending from

about 0 mm outside of the optic zone to about 1 mm inside of the lens edge, wherein the convex surface is a surface calculated from topographic measurements, wavefront measurements, or combinations thereof.

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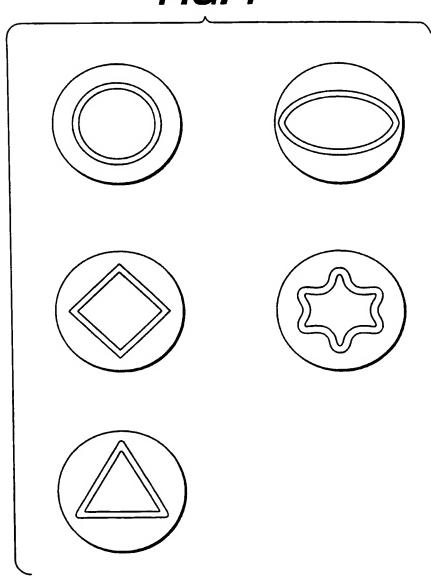
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- 19. The lens of claim 18, wherein the surface on which the coaxial stabilization zone is located is a surface calculated from topographic measurements
- 20. The lens of claim 11, wherein the surface on which the coaxial stabilization 2 zone is located is a surface calculated from wavefront measurements.
 - 21. The lens of claim 18, 19, or 20, wherein the coaxial stabilization zone comprises a single thickened area at about the 270° axis.
- The lens of claim 11, wherein the coaxial stabilization zone is substantially circular.
 - 23. A method for producing contact lenses comprising the steps of: a.) defining a coaxial stabilization zone for at least one surface of a contact lens; b.) determining parameters for at least one area of thickness within the coaxial stabilization zone; and c.) calculating a surface design for the at least one surface.
 - 24. The method of claim 23, wherein step b.) comprises determining a contour for the at least one coaxial stabilization zone using a function selected from the group consisting of linear functions and their derivatives, sine or cosine functions and their derivatives, exponential functions, Gaussian functions, conic functions such as circles, ellipses, parabolas, hyperbolas, and the like, cycloid functions, splines, polynomial functions of any order, filter functions, notch functions, bandpass filter functions, Witch of Agnesi functions, hyperbolic trigonometric functions, catenary functions, and the like, and combinations thereof.

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- 25. The method of claim 24, wherein the function is one of linear function to exponential values, sine or cosine phase shifted exponential functions, Gaussian
- 5 functions, or Witch of Agnesi functions.

FIG. 1



SUBSTITUTE SHEET (RULE26)

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER IPC 7 G02C7/04						
	International Patent Classification (IPC) or to both national classification	cation and IPC				
B. FIELDS	SEARCHED cumentation searched (classification system followed by classification)	tion symbols				
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C. DOCUM	ENTS CONSIDERED TO BE RELEVANT					
Category °	Citation of document, with indication, where appropriate, of the r	elevant passages	Relevant to claim No.			
A	US 5 009 497 A (COHEN ALLEN L) 23 April 1991 (1991-04-23) column 1, line 55 -column 2, line 31		1-4,11, 12,16,18			
A	WO 92 22845 A (NEWMAN STEVE) 23 December 1992 (1992-12-23) page 1, line 35 -page 5, line 9	1-3,11, 18				
A	EP 0 439 424 A (CIBA GEIGY AG) 31 July 1991 (1991-07-31) page 4 -page 6, line 27		1,6,11, 18,23			
Fun	ther documents are listed in the consnuation of box C.	Patent family members are listed in	n annex.			
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T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention. *E* earlier document but published on or after the international. *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention. *Y* document of particular relevance invention.						
X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to invention which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *X* document of particular relevance; the claimed invention inventive an inventive step when the document is taken alone cannot be considered to involve an inventive step when the						
O document referring to an oral disclosure, use, exhibition or other means document is combined with one or more other such document other means, such combination being obvious to a person skilled in the art.						
later than the priority date claimed "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report						
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INTERNATIONAL SEARCH REPORT

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In 1al Application No PCT/US 00/23424

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5009497	Α	23-04-1991	NONE	
WO 9222845	A	23-12-1992	AU 667670 B CA 2111466 A EP 0589959 A NZ 243183 A US 5500695 A	04-04-1996 23-12-1992 06-04-1994 28-05-1996 19-03-1996
EP 0439424	A	31-07-1991	AT 119689 T AU 629725 B AU 6934591 A CA 2034719 A DE 59104829 D DK 439424 T ES 2069256 T GR 3015347 T HK 1000293 A IE 65624 B IL 96970 A JP 3004741 B JP 5034644 A PT 96541 A US 5166710 A	15-03-1995 08-10-1992 25-07-1991 25-07-1991 13-04-1995 27-03-1995 01-05-1995 30-06-1995 20-02-1998 01-11-1995 07-10-1994 31-01-2000 12-02-1993 15-10-1991 24-11-1992